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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GANESAN, SUBA	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
11/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/603,115	DING ET AL.	
	Examiner	Art Unit	
	Suba Ganesan	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *111-170* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *111-170* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/2007 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 111-113, 120-121, 124-125, 129-130, 136-137, 139-143, 150-151, 154-155, 159-160, 166-167 and 169-170 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (5,464,650). Berg et al. discloses a vascular stent having at least a portion which is implantable into the body of a patient, wherein at least a part of the stent portion is stainless steel (col. 3, lines 37-41) covered with a coating for release of a biologically active material, wherein said coating adheringly conforms to the stent structure and comprises an undercoat comprising an ethylene vinyl acetate

copolymer material incorporating an amount of biologically active material therein for timed release therefrom which acts to inhibit smooth muscle cells in said patient (col. 4, line 35- col. 5, line 39), and wherein said coating further comprises a topcoat which at least partially covers the undercoat, said topcoat comprising a biostable, non-thrombogenic polymeric material which provides long term non-thrombogenicity to the stent portion during and after release of the biologically active material, and wherein said topcoat is ***substantially free of an elutable material***, i.e. ethylene vinyl acetate copolymer. Therapeutic substances, i.e. hirudin, are well known to one of ordinary skill in the art to inherently inhibit smooth muscle cell proliferation (i.e. Vlasuk et al. 5,492,895, col. 5, lines 36-59). Berg et al. discloses that the coating can comprise several layers, therefore having an undercoat and a topcoat. However Berg et al fails to disclose the topcoat ***free*** of an elutable material.

As noted in MPEP 2144.05 (I), "a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties." "Substantially free" is close enough to free "that one skilled in the art would have expected them to have the same properties."

Differences in concentration do not support the patentability of subject matter unless there is evidence indicating such concentration is critical. The present specification discloses criticality in regards to the topcoat ***substantially free*** of an elutable material, not entirely free of an elutable material.

In addition, as noted in the Applicant's response:

"Moreover, the nature of the invention, i.e., coating a stent with a drug-free, pure polymer, is straightforward and not unduly complicated. The relative skill of those in the art of coating stents is high, and the art of coating stents is predictable. Finally, the breadth of the claims is reasonable and not overly broad. Thus, Applicants submit that the instant specification fully enables one of skill in the art to make and use the invention commensurate in scope with the claims without undue experimentation."

Therefore it would be obvious to one of ordinary skill to have the topcoat free of an elutable material because they would expect it to have the same properties as a topcoat substantially free of an elutable material, and it would not require undue experimentation to determine the optimal amount of elutable material within the topcoat.

Claims 114-119, 122-123, 126-128, 131-135, 138, 144-149, 152-153, 156-158, 161-165 and 168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (5,464,650) as above, in further view of Mitchell et al. (5,288,711). Berg et al. discloses a coated vascular stent as above however Berg et al. also fails to disclose the coating comprising an antibiotic. Mitchell et al. teaches a stent comprising an antibiotic (Rapamycin) to inhibit proliferation of vascular smooth muscle cells (col. 3, lines 7-31). It would have been obvious to one of ordinary skill in the art to combine the teaching of a stent comprising an antibiotic, as taught by Mitchell et al., to a coated vascular stent as per Berg et al., in order to inhibit proliferation of vascular smooth muscle cells.

Response to Arguments

Applicant's arguments filed May 17, 2007 have been fully considered but they are not persuasive.

As noted in prior office actions, Berg et al discloses a plurality of layers, therefore at least an undercoat and topcoat. In column 2, lines 44-67, Berg et al discloses:

> "The release rate can be further controlled by varying the ratio of drug to polymer in the multiple layers.

Although Berg discloses an example in which the outer layers have a higher ratio of drug-to-polymer than the inner layers, this does not preclude a configuration in which the outer layer has a lower ratio of drug-to-polymer than the inner layers. Equipped with the disclosure of Berg that varying the ratio of drug to polymer in multiple layers controls the release rate, one of ordinary skill in the art would have found it obvious to try various amounts of drug eluting material on either layer.

Berg et al suggests a topcoat that is substantially free of an elutable material. In column 5, lines 12-18, Berg discloses:

> "More polymer may be needed if it has relatively poor efficacy in retaining the therapeutic substance on the stent and more polymer may be needed in order to provide an elution matrix that limits the elution of a very soluble therapeutic substance. A wide ratio of therapeutic substance to polymer could therefore be appropriate and could range from about 10:1 to about 1:100."

Therefore the therapeutic substance to polymer ratio of 1:100 could easily be considered substantially free of an elutable material. As noted above, "Substantially free" is close enough to free that one skilled in the art would have expected the topcoat of Berg to have the same properties as the present invention. Berg's disclosure of a wide range of therapeutic substance to polymer ratios *includes* the endpoints of the ranges; more specifically, Berg's ranges include a therapeutic substance to polymer ratio that is substantially free of elutable material. The disclosure of a ratio of 1:100 indicates that Berg does not teach away from having a ratio substantially free of elutable material.

Equipped with the disclosure of Berg that varying the ratio of drug to polymer in multiple layers controls the release rate as well as the disclosure of a therapeutic substance to polymer ratio of 1:100, one of ordinary skill in the art at the time of the invention would have found it obvious to vary the amount of drug on each layer using the specified drug ratio disclosed by Berg, the motivation to try such a modification being: creating a more specifically controlled drug release rate.

The examiner does not believe that any of the claims require a different polymer in the undercoat and topcoat.

Berg discloses the use of hydrophobic and biostable polymers, which not only suggests their use but also indicates that Berg is not teaching away from these materials. Berg discloses use of anti-coagulants (col. 5 lines 19-40), which the examiner is considering to be the same as non-thrombogenic material.

Conclusion

2. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suba Ganesan whose telephone number is 571-272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDG 11/8/2007

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E Pellegrino